

REMARKS

Claims 1-43 are currently pending in the application. Claims 8, 11-21, and 29-42 were previously withdrawn. Applicant respectfully requests reconsideration of the pending claims in view of the following remarks.

Claim Rejections - 35 U.S.C. § 102

The Examiner rejected Claims 1-7, 9-10, and 22-28 under 35 U.S.C. § 102 as anticipated by Hou.

Hou does not anticipate the subject matter of independent Claim 1. Specifically, Hou does not disclose a chromatography cartridge including a first plug positioned within a first open end and having an outer circumferential surface, a substantial portion of the outer circumferential surface being fused to the inner surface of the tubular housing.

Rather, Hou discloses a cartridge 10 including a cylindrical tube 13 and a cylinder end cap 36. The end cap 36 is connected to the top edge 31 of the cylinder 13. The outer circumferential surface of the end cap 36 is not connected to the inner surface of the cylindrical tube 13. Moreover, the outer circumferential surface of the end cap 36 is positioned on the exterior of the cylindrical tube 13 and does not contact any portion of the cylindrical tube 13.

Accordingly, Hou does not disclose the subject matter of independent Claim 1. Accordingly, independent Claim 1 is allowable. Claims 2-7, 9, and 10 depend from Claim 1, and are allowable for the same and other reasons.

Hou does not anticipate the subject matter of independent Claim 22. Specifically, Hou does not disclose a chromatography cartridge including a first plug positioned within a first open end of the tubular housing and having an outer circumferential surface, at least a portion of the outer circumferential surface being fused to the inner surface of the tubular housing.

Rather, Hou discloses a cartridge 10 including a cylindrical tube 13 and a cylinder end cap 36. The end cap 36 is connected to the top edge 31 of the cylinder 13. The outer circumferential surface of the end cap 36 is not connected to the inner surface of the cylindrical tube 13. Moreover, the outer circumferential surface of the end cap 36 is positioned on the exterior of the cylindrical tube 13 and does not contact any portion of the cylindrical tube 13.

Accordingly, Hou does not disclose the subject matter of independent Claim 22. Accordingly, independent Claim 22 is allowable. Claims 23-28 depend from Claim 22 and are allowable for the same and other reasons.

Claim Rejections - 35 U.S.C. § 103

The Examiner has rejected:

(a) Claims 1-7, 9-10, and 22-28 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,693,223 ("Yamada") in view of U.S. Patent No. 6,280,619 ("Lacy") and U.S. Patent No. 6,953,526 ("Fritze").

(b) Claims 1-7, 9-10, and 22-28 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,360,544 ("Nakaso") in view of Lacy and Fritze.

(c) Claims 7 and 28 under 35 U.S.C. § 103(a) as being unpatentable over Yamada in view of Lacy and Fritze, and further in view of U.S. Patent No. 6,454,891 ("Goss").

(d) Claims 7 and 28 under 35 U.S.C. § 103(a) as being unpatentable over Nakaso in view of Lacy and Fritze, and further in view of Goss.

(e) Claim 9 under 35 U.S.C. § 103(a) as being unpatentable over Yamada in view of Lacy and Fritze, and further in view of Hou.

(f) Claim 9 under 35 U.S.C. § 103(a) as being unpatentable over Nakaso in view of Lacy and Fritze, and further in view of Hou.

(g) Claims 1-7, 9-10, and 22-28 under 35 U.S.C. § 103(a) as being unpatentable over Hou in view of Lacy and Fritze.

(h) Claims 7 and 28 under 35 U.S.C. § 103(a) as being unpatentable over Hou in view of Lacy and Fritze, and further in view of Goss.

Applicant respectfully contends that none of the cited references discloses a chromatography cartridge comprising a tubular housing and a first plug fused to the inner surface of one end of the tubular housing and a second plug fused to the inner surface of a second end of the tubular housing.

In the Office Action, the Examiner reasoned that:

It would have been obvious to spin weld in either Yamada or Nakaso because Lacy discloses spin welding a cap to the cartridge to "meld their adjacent surfaces together" for the obvious purpose of preventing leaking and Fritze confirms spin welding minimizes leaks.

(Office Action, page 2-3.) Applicant respectfully disagrees because, as discussed below, objective evidence of secondary considerations confirms that the claimed invention has satisfied a long-felt need in the chromatography industry, and therefore, is nonobvious and patentable over the cited references. In support of the nonobviousness of the claimed invention, Applicant

submits herewith a Declaration of Nicholas DeMarco Under 37 C.F.R. § 1.132 ("DeMarco Declaration").

I. The Claimed Invention

The claimed invention includes a chromatography cartridge comprising a tubular housing, a first plug, and a second plug. The tubular housing includes a first open end, a second open end, and an inner surface. The first plug is positioned within the first open end and has an outer circumferential surface, a substantial portion of the outer circumferential surface being fused to the inner surface of the tubular housing. The second plug is positioned within the second open end and has an outer circumferential surface, a substantial portion of the outer circumferential surface being fused to the inner surface of the tubular housing.

II. Secondary Consideration of Long-Felt Need Demonstrates Nonobviousness of the Claimed Invention

Applicant submits herewith objective evidence of the claimed invention's satisfaction of a long-felt need.

A. Secondary Considerations of Nonobviousness Must Be Considered

Obviousness under 35 U.S.C. § 103 is a legal conclusion which requires the resolution of four preliminary factual inquiries:

- 1) the scope and content of the prior art;
- 2) the differences between the claims and the prior art;
- 3) the level of ordinary skill in the pertinent art; and
- 4) secondary considerations, if any, of nonobviousness.

See Uniroyal v. Rudkin-Wiley Corp., 837 F.2d 1044, 1050 (Fed. Cir. 1988), *cert. denied*, 488 U.S. 825 (1988).

Secondary considerations include objective indicia of nonobviousness such as commercial success due to the invention, long-felt but unresolved need, and copying of the invention in preference to copying the prior art. *See Graham v. John Deere & Co.*, 383 U.S. 1, 17-18 (1966); *Panduit Corp. v. Dennison Mfg.*, 810 F.2d 1561, 1566-1568 (Fed. Cir. 1987), *cert. denied*, 481 U.S. 1052 (1987). Such objective evidence of obviousness must always when present be considered en route to a determination of obviousness because: evidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not. It is to be considered as part of all the evidence, not just when the decisionmaker

remains in doubt after reviewing the art. *Uniroyal*, 837 F.2d at 1053 (emphasis added) (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983)). See also *Graham*, 383 U.S. at 35; *Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720, 725 (Fed. Cir. 1990) (“an analysis of obviousness must address objective evidence of nonobviousness”). Although often termed “secondary,” the Federal Circuit has noted that these objective factors highlighted in *Graham v. John Deere* are often the most probative evidence of nonobviousness, because all other evidence is potentially tainted by hindsight. *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). See *Stratoflex*, 713 F.2d at 1538; *In Re GPAC, Inc.*, 57 F.3d 1573, 35 U.S.P.Q.2d 1116, 1121 (Fed. Cir. 1995). Numerous decisions rely upon facts showing a long-felt need for an invention, and the failure of others to meet that need, as evidence probative of patentability. See, e.g., *Goodyear Tire & Rubber v. Ray-O-Vac*, 321 U.S. 275; *Eibel Process v. Minnesota & Ontario Paper*, 261 U.S. 45, 53-54, 68 (1923); *Great Northern Corp. v. Henry Molded Prods.*, 864 F. Supp. 865 (E.D. Wis. 1994). As one court noted:

The existence of an enduring, unmet need is strong evidence that the invention is novel, not obvious, and not anticipated. If people are clamoring for a solution, and the best minds do not find it for years, that is practical evidence—the kind that can't be bought from a hired expert, the kind that does not depend on fallible memories or doubtful inferences—of the state of knowledge.

In re Mahurkar Patent Litig., 831 F. Supp. 1354, 1378 (N.D. Ill. 1993), *aff'd*, 71 F.3d 1573 (Fed. Cir. 1995).

B. MPEP Long-Felt Need Standard

According to the *Manual of Patent Examining Procedure*, objective evidence used to establish long-felt need and failure of others requires that the need (1) must have been a persistent one recognized by those of ordinary skill in the art; (2) must not have been satisfied by another before the invention by the applicant; and (3) must be satisfied by the invention. MPEP § 716.04.

C. Declaration of Nicholas DeMarco Under 37 C.F.R. § 1.132

In support of the long-felt need and therefore, the nonobviousness of the claimed invention, attached hereto is the above-mentioned DeMarco Declaration. Mr. DeMarco is the inventor of the claimed invention and the President of Analogix, Inc. (“Analogix”), the assignee of the present patent application. The DeMarco Declaration demonstrates the long-felt but unmet need for a spin-welded chromatography cartridge capable of leak-free performance and

maintaining silica bed compaction; that this need had not been met by any other prior art technology; and that the claimed invention in fact satisfies this need.

Persistent Need

The claimed invention meets the first requirement for long-felt need under the *MPEP* - that “the need must have been a persistent one that was recognized by those of ordinary skill in the art.” *MPEP* § 716.04. Prior to the introduction of the claimed invention, the chromatography cartridge industry experienced a persistent need for larger, leak-proof cartridges. DeMarco Decl. ¶¶ 11-13. This persistent need for a solution has been recognized by those of ordinary skill in the art. DeMarco Decl. ¶ 7.

The increased popularity of pre-packaged chromatography cartridges over the past several years drove the increase in demand for larger cartridges. DeMarco Decl. ¶ 14. For several years, the chromatography cartridge industry unsuccessfully sought solutions to larger cartridges and leaking cartridges. DeMarco Decl. ¶¶ 16-19.

Long-Felt Need Not Satisfied By Another

The claimed invention also meets the second requirement for long-felt need under the *MPEP*—that the “long-felt need must not have been satisfied by another before the invention by applicant.” *MPEP* § 716.04. The conventional view in the industry prior to the claimed invention was to use off-the-shelf components for the chromatography cartridge. DeMarco Decl. ¶¶ 9, 12-13. Industry analysis devoted to the claimed invention acknowledges that despite this conventional view in the industry and the numerous competitors therein, Applicant was the first to satisfy the need. DeMarco Decl. ¶ 15. In fact, Applicant was the first to forge a new path in the design of pre-packaged chromatography cartridges and rejected conventional wisdom of using off-the-shelf components. *Id.*

Invention Satisfies Need

Lastly, the claimed invention meets the third requirement for long-felt need under the *MPEP*—that “the invention must in fact satisfy the long-felt need.” *MPEP* § 716.04. As the DeMarco Declaration establishes, the claimed invention does in fact satisfy the chromatography cartridge industry’s long-felt need described above. DeMarco Decl. ¶ 26-29. The tests, which were conducted in our laboratory, and the positive customer feedback we have received

indicate that Analogix' spin-welded chromatography cartridge outperformed our competitors' chromatography cartridges. *Id.*

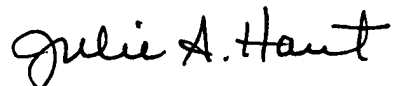
For at least the above reasons, the claimed invention fulfills the long-felt need described above, and therefore satisfies the third requirement for long-felt need under the *MPEP*.

Since the DeMarco Declaration submitted herewith establishes long-felt need as to all three requirements under the *MPEP*, Applicants respectfully submit that the claimed invention is nonobvious and that the Examiner's rejections should be withdrawn.

CONCLUSION

In view of the foregoing, allowance of Claims 1-7, 9, 10 and 22-28 is respectfully requested. The undersigned is available for telephone consultation during normal business hours.

Respectfully submitted,

A handwritten signature in black ink that reads "Julie A. Haut". The signature is written in a cursive, flowing style.

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